

Associated Laser Productions International, Inc.

Consultants for All Laser Entertainment Applications

5719 '00 JUL 13 P1:11

7/6/2000

To: Dockets Management Branch (HFA-305)
Food and Drug Administration, Room 1-23
12420 Parkland Drive
Rockville, MD 20852

To whomever is in receipt of this document, my name is Robert J Ruhl with Associated Laser Productions International, Inc. I have been contracted as laser safety officer for the George Carden Circus International. I also have the full authority of George Carden Circus International to perform these duties. In-closed you will find an annual report covering the three year reporting period 1997 / 1999 of this variance. I am also requesting a variance renewal in conformance with 21 CFR 1010.4 for George Carden Circus International, docket No.97V-0095 / accession No. 97A0089. I am also sending along with this letter a Light Show / Supplemental report.

As you will find in the Supplemental Light Show Report, there are several changes to the existing variance. I will list them in this letter as well as in the complete Light Show Report. Please feel free to contact me if there are and questions you may have in regards to this Annual / Renewal / Supplemental request. My telephone number is 1-509-924-0661 Fax number 1-509-228-0222 email dr_laser@nidlink.com URL www.dr-laser.com.

Thank you very much for all your help and concern in this matter please feel free to call with any questions you may have. As I will assist in any way needed to expedite this request.

Sincerely,

Bob Ruhl

Associated Laser Productions International, Inc. / Doctor Laser Light Shows • East 8309 Broadway, Spokane, WA 99212
(509) 924-0661 • E mail: www.dr-laser.com

97V-0095

RPT1

These are the supplemental changes to be made to our Light Show Variance # 97V-0095

SUPPLEMENTAL ITEMS AS THEY APPEAR ON FORM 21 CFR 1040.11 (c)

- #8 Laser Radiation Levels: Argon / YAG 457.9 –532 nm 40 WATTS**
- #14 Remarks to Read: George Carden Circus International will only use equipment from companies manufacturing certified projectors. From time to time rental equipment will be required in the normal course of business, in the event rental equipment is used we will only use equipment from companies with a proper and current CDRH variance.**

SAMPLE: Las Vegas Lasers & Certified Projectors from companies holding a proper CDRH variance.

**PART 2
IDENTIFICATION OF REPORT**

- 2.3 Accession number: 97A0089
Date: Mar 26 1997**
- 2.4 Date of this report: Wednesday, April 26, 2000**

**PART 10
LASER RADIATION LEVELS**

- 10.1 Our use of lasers and power levels for any display would fall within general light show industry normal levels and the capability of our existing equipment**

EXAMPLE: based on laser light show display and practices.

- 1. Beam effects from 2 to 40 watts**
- 2. Screen effects from ½ to 5 watts**

All other effects would be at minimum power levels.

ATTACHMENT to Part 14.1

DAILY PERFORMANCE CHECK LIST REV 3 02-2000

ATTACHED TO LIGHT SHOW REPORT

ATTACHMENT TO PART 15.1

STATE NOTIFICATIONS

Manuel Karos

1 (301) 594-4648

x 149

Sean Boyd

1(301) 594-4654

ATTACHMENT TO PART 15.1

NOTIFICATION TO CDRH OF SHOW

ATTACHED TO LIGHT SHOW REPORT

LASER PRODUCT/LASER LIGHT SHOW ANNUAL REPORT: Page 1

Part 1. Identification of Manufacturer

Report Date: June 5, 2000

Company Name: George Carden Circus International

Address: 3901 West State Highway O, Springfield, Missouri, 65803

Corresponding Official signature: _____

Name & title Robert J Ruhl, Safety Consultant

Telephone: 1 (509) 924-0661

Firm name & address, if different from above _____

This Annual Report is submitted in accordance with 21 CFR 1002.13 for the period July 1, 1997 through June 30, 1999.

Part 2. Production Status

- () Products were manufactured during this period and the firm is still in business. If you check this, complete and mail this entire report.
- () No products were manufactured during this period but the firm is still in business and expects to manufacture in the future. If you check this, complete Part 6 and mail pages 1 and 4.
- () No products were manufactured during this period and the firm is now out of business. If you check this, complete Part 6 and mail pages 1 and 4.
- () Products were manufactured during this period but the firm is now out of business. If you check this, complete and mail this entire report.

Part 3. Current Production Tabulation3.1. All Laser Products

Accession Number	Family Designation	Selling Model Numbers	Product Function	Class	Production Status		
					Active	Discont (mo/yr)	Plant

3.2. Laser Light Shows

Accession Number	Projector or Show Family Designation	Permanent or Touring	Class	Lazing Media	Production status	
					No. Shows Performed	Discont. (mo/yr)
97A0089	Las Vegas Laser LT-1000	N/A	IIIa	N/A	0	N/A

Note:

There were no Laser Shows Produced under Accession Number 97A0089 during the Period specified in this document.

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICES FOOD AND DRUG ADMINISTRATION	APPLICATION FOR A VARIANCE FROM 21 CFR 1040.11(c) FOR A LASER LIGHT SHOW, DISPLAY, OR DEVICE	Form Approved: 0910-0025 Expiration Date October 31, 2000 See Page 4 for OMB Statement. DOCKET NUMBER 97A-0095
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NOTE: No laser light show, projection system, or device may vary from compliance with 21 CFR 1040.11(c) in design or use without the approval of this Application in accordance with 21 CFR 1010.4.

INSTRUCTIONS

1. Check all applicable boxes and type or print the requested Information.

2. Submit an original and four (4) copies.

3. Mail your application to the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 1-23, 12420 Parkland Drive, Rockville, MD 20852.

4. Enter Document Number if assigned.

1. NAME OF COMPANY **George Carden Circus International**

2. ADDRESS OF COMPANY (Include ZIP CODE) (If P.O. Box is used, include actual street address also.)
3901 West State Highway O, Springfield, Missouri 65803

3. NAME AND TITLE OF RESPONSIBLE PERSON
Charles V Amaral, Jr., Eastern Unit Manager

4. TELEPHONE NO. (Include area code)
1 (417) 833-3588

5. DATE OF SUBMISSION
June 5-2000

6. The applicant requests the variance to be in effect for a period of 2 years from the date of issue.
 (In general, the Agency will approve a Variance for only two years. If a longer period is requested, a justification must be attached as part of the application.)

7. PRODUCT DESCRIPTION AND USE

a. LIST NAME AND/OR MODEL NUMBER(S) FOR THE LASER LIGHT SHOW(S) AND PROJECTOR(S)
George Carden Circus International

b. PRODUCT FOR WHICH A VARIANCE IS REQUESTED
☐ A LASER DISPLAY DEVICE
☐ A PROJECTOR FOR A LASER LIGHT SHOW
☒ A LASER LIGHT SHOW
☒ OTHER (Specify) _____ **AS PER NOTIFICATION**

c. ☐ PROJECTORS ARE INTENDED FOR RESALE, LEASE, OR LOAN TO OTHER LASER LIGHT SHOW PRODUCERS

d. PRODUCT IS INTENDED FOR USE IN A
☒ PLANETARIUM OR OTHER DOME PROJECTION STRUCTURE
☒ THEATER
☒ HOTEL/MOTEL BALLROOM OR MEETING ROOM
☒ STORE DISPLAY
☒ TRADE SHOW OR CONVENTION
☒ DISCOTHEQUE OR NIGHT CLUB
☒ PAVILION
☒ INDOOR ARENA
☒ OUTDOOR ARENA
☒ MUSEUM
☒ OUTDOOR UNENCLOSED AREA
☒ OTHER (Specify) _____ **AS PER NOTIFICATION**

e. PRODUCT IS INTENDED TO BE USED
☐ AT ONLY ONE (Fixed) Location
☒ AT A VARIETY OF (Tour) LOCATIONS
☒ OTHER (Specify) _____ **AS PER NOTIFICATION**

f. PRODUCT IS INTENDED TO BE USED AT ANY ONE LOCATION
☒ MORE THAN 15 DAYS
☒ MORE THAN 5 BUT NOT MORE THAN 15 DAYS
☒ LESS THAN 5 DAYS

g. TOUR IS INTENDED TO RUN FOR
☐ MORE THAN 6 MONTHS
☐ 1-6 MONTHS
☐ LESS THAN 1 MONTH
☒ NOT APPLICABLE (Not a tour)
☒ OTHER (Specify) _____ **AS PER NOTIFICATION**

h. PRODUCT UTILIZES THE FOLLOWING LASER EFFECTS
☒ FRONT SCREEN PROJECTIONS
☒ REAR SCREEN PROJECTIONS
☒ HOLOGRAPHIC DISPLAYS
☒ MULTIPLE REFLECTIONS/DIFFRACTION EFFECTS
☐ AUDIENCE SCANNING
 (Also includes scanning any accessible uncontrolled areas)
☒ REFLECTIONS FROM STATIONARY MIRRORS OR MIRRORED SURFACES (Beam Matrices)
☒ STATIONARY IRRADIATION OF ROTATING MIRRORS BALLS, ETC.
☒ SCANNING IRRADIATION OF ROTATING MIRROR BALLS, ETC.
☒ FIBER OPTIC PROJECTIONS
☒ FOG, SMOKE, OR OTHER SCATTERING ENHANCEMENT EFFECTS
☒ OTHER (Specify) _____ **AS PER NOTIFICATION**

8. LASER RADIATION LEVELS

LASER MEDIUM (Ar, He-Ne, ect.)	WAVE LENGTHS (nm)	PEAK POWER (Watts)
KRYPTON	400 - 700 nm	8 WATTS
ARGON / YAG	457.9 - 532 nm	40 WATTS
ARGON / KRYPTON (WHITE	457.9 - 676.4 nm	20 WATTS

9. IF ANY LASER RADIATION IS PULSED OR SCANNED, GIVE THE PULSE DURATION AND RATE AND SCANNING FREQUENCY AND AMPLITUDE
SCANNING BAND WIDTH FROM DC TO 5 KHz MODULATION IN BOTH COLOR AND INTENSITY FROM DC TO 100 KHz.

10. REASON FOR REQUESTING VARIANCE
☒ COMPLIANCE WITH THE LIMITS OF 21 CFR 1040-11(c) WOULD RESTRICT THE INTENDED USE OF THE PRODUCT BECAUSE COMPLIANCE WOULD LIMIT THE OUTPUT
☐ OTHER OR ADDITIONAL EXPLANATION (Specify)

11. MANNER IN WHICH IT IS PROPOSED TO DEVIATE FROM THE REQUIREMENTS OF THE APPLICATION STANDARD

☒ IT IS PROPOSED TO DEVIATE FROM THE PROVISIONS OF 21 CFR 1040.11(c) IN THAT THE ACCESSIBLE EMISSION LEVEL WOULD EXCEED THE ACCESSIBLE EMISSION LIMITS SPECIFIED IN 21 CFR 1040.11(c)

☐ IT IS PROPOSED TO DEVIATE FROM THE PROVISIONS OF 21 CFR 1040.11(c) AS FOLLOWS:

12. ADVANTAGES TO BE DERIVED FROM SUCH DEVIATION

☒ LASER LIGHT SHOWS AND DISPLAYS ARE ACCEPTED POPULAR MEDIA IN ENTERTAINMENT AND THE ARTS OF POWER LEVELS IN EXCESS OF THE LIMITS IMPOSED BY 21 CFR 1040.11(c) IS NECESSARY TO ACHIEVE THE REQUIRED EFFECTS IN THESE MEDIA.

☐ OTHER OR ADDITIONAL ADVANTAGES (describe and explain)

13. EXPLAIN THE ALTERNATE MEANS OF RADIATION PROTECTION TO BE PROVIDED. (Check as many boxes as apply, in item 14 "Remarks," justify any boxes not checked, using additional sheets as necessary, State any other means of radiation that will be used.)

- a. ☒ ALL LASER PRODUCTS, SYSTEMS, SHOWS, AND PROJECTORS WILL BE CERTIFIED TO COMPLY WITH 21 CFR 1040.10 AND THE CONDITIONS OF THIS VARIANCE AND WILL BE REPORTED AS REQUIRED BY 21 CFR 1002.10 AND 1002.12 USING THE REPORTING GUIDE PROVIDED FOR SUCH PURPOSE. THESE ACTIONS WILL BE ACCOMPLISHED PRIOR TO ANY INTRODUCTION INTO COMMERCE.
- b. ☒ EFFECTS NOT SPECIFICALLY INDICATED IN THIS VARIANCE APPLICATION WILL NOT BE PERFORMED, NO OTHER EFFECTS WILL BE ADDED UNTIL AN AMENDMENT TO THE VARIANCE HAS BEEN OBTAINED AND THE REQUIRED REPORTS OR SUPPLEMENTS, AS APPLICABLE, HAVE BEEN SUBMITTED.
- c. ☒ SCANNING, PROJECTION, OR REFLECTION OF LASER AND COLLATERAL RADIATION (LIGHT SHOW RADIATION) INTO AUDIENCE OR OTHER ROLLED AREAS WILL NOT BE PERMITTED EXCEPT FOR DIFFUSE REFLECTIONS PRODUCED BY THE ATMOSPHERE, ADDED ATMOSPHERIC SCATTERING MEDIA, AND TARGET SCREENS.
- d. ☒ LASER RADIATION LEVELS IN EXCESS OF THE LIMITS OF CLASS 1 WILL NOT BE PERMITTED AT ANY POINT LESS THAN 3.0 METERS ABOVE ANY SURFACE UPON WHICH PERSONS OTHER THAN OPERATORS, PERFORMERS, OR EMPLOYEES ARE PERMITTED TO STAND OR 2.5 METERS BELOW OR IN LATERAL SEPARATION FROM ANY PLACE WHERE SUCH PERSONS ARE PERMITTED TO BE. OPERATORS, PERFORMERS, AND EMPLOYEES WILL NOT BE REQUIRED OR ALLOWED TO VIEW RADIATION ABOVE THE LIMITS OF CLASS 1 OR BE EXPOSED TO RADIATION ABOVE THE LIMITS SPECIFIED IN 21 CFR 1040.11(c).
- e. ☐ ANY PRODUCT WHICH RELIES ON SCANNING TO MEET ACCESS, EXPOSURE, OR PRODUCT CLASS LIMITS WILL INCORPORATE A SCANNING SAFEGUARD SYSTEM WHICH DIRECTLY SENSES SCANNER MOTION AND WHICH WILL REACT FAST ENOUGH TO PRECLUDE EXCEEDING THE APPLICABLE LIMIT.
- f. ☒ ALL LASER LIGHT SHOWS SHALL BE UNDER THE DIRECT AND PERSONAL CONTROL OF TRAINED, COMPETENT OPERATOR(S). THE OPERATOR(S) WILL:
 - (1) IMMEDIATELY TERMINATE THE EMISSION OF LIGHT SHOW RADIATION IN THE EVENT OF ANY UNSAFE CONDITION;
 - (2) BE LOCATED WHERE ALL BEAM PATHS CAN BE DIRECTLY OBSERVED AT ALL TIMES; AND
 - (3) BE AN EMPLOYEE OF THE VARIANCE HOLDER WHO WILL BE RESPONSIBLE FOR THE TRAINING AND CONDUCT OF THE OPERATOR.
- g. ☒ THE MAXIMUM LASER PROJECTOR OUTPUT POWER WILL NOT EXCEED THE LEVEL REQUIRED TO OBTAIN THE INTENDED EFFECTS.
- h. ☒ THE PROJECTION SYSTEM (I.E., THE PROJECTOR AND ALL OTHER COMPONENTS USED TO PRODUCE THE LIGHTING EFFECTS) WILL BE SECURELY MOUNTED OR IMMOBILIZED TO PREVENT UNINTENDED MOVEMENT OR MISALIGNMENT, BEAM LIMITERS WILL BE PROVIDED AS AN INHERENT PART OF THE SYSTEM DESIGN TO PREVENT OVERFILLING OF SCREENS, BEAM STOPS, TARGETS, ETC.
- i. ☐ LASER PROJECTORS WILL NOT BE DELIVERED TO ANY OTHER PARTY UNDER AN AGREEMENT OF SALE, LEASE, OR LOAN UNLESS AND UNTIL THE RECIPIENT DEMONSTRATES THAT THEY HAVE A VARIANCE IN EFFECT AT THE TIME OF DELIVERY THAT PERMITS THEM TO PRODUCE LASER LIGHT SHOWS INCORPORATING SUCH PROJECTOR.
- j. ☒ IN ADDITION TO THE REQUIREMENTS OF 21 CFR 1040.10(h), THE MANUFACTURE OF LASER PROJECTORS/SYSTEMS WILL PROVIDE TO PARTIES WHO PURCHASE, LEASE, OR BORROW THE EQUIPMENT, ADEQUATE USER'S INSTRUCTIONS FOR SAFE INSTALLATION AND OPERATION AND WHICH EXPLAIN THE RESPONSIBILITY OF THE RECIPIENT AS AN INDEPENDENT LIGHT SHOW MANUFACTURER TO SUBMIT THE REQUIRED REPORTS AND APPLY FOR AND OBTAIN A VARIANCE FROM CDRH PRIOR TO INTRODUCTION INTO COMMERCE OF ANY LASER LIGHT SHOW.
- k. ☒ THE REQUIREMENTS OF 21 CFR 1002.30(a)(1) AND (2) WILL BE ACCOMPLISHED THROUGH THE USE OF WRITTEN PROCEDURES FOR SETUP, ALIGNMENT, TESTING, AND PERFORMANCE OF EACH SHOW. THESE PROCEDURES WILL BE IN SUFFICIENT DETAIL TO ENSURE COMPLIANCE WITH 21 CFR 1040.10, THE CONDITIONS OF THIS VARIANCE, AND THE CONTROL OF ACCESS TO RADIATION AREAS USING THE PROCEDURES DESCRIBED IN THE ANSI Z 136.1 STANDARD FOR THE SAFE USE OF LASERS (AMERICAN NATIONAL STANDARDS INSTITUTE, 1430 BROADWAY, NEW YORK, NY 10018) OR ANY OTHER EQUIVALENT USER CONSENSUS STANDARD AND, WHERE APPLICABLE, STATE OR LOCAL REQUIREMENTS, LASER RADIATION RES WHICH CAN CONTAIN RADIATION LEVELS ABOVE THE LIMITS SPECIFIED IN 21 CFR 1040.11(c), WILL BE CLEARLY IDENTIFIED BY THE POSTING OF WARNING SIGNS AND/OR RESTRICTING ACCESS THROUGH PHYSICAL MEANS (SUCH AS PRESSURE SWITCHES, PHOTOCCELL, BARRIERS, GUARDS, ECT.) THESE REQUIREMENTS APPLY TO TEMPORARY AREAS (SUCH AS DURING SET-UP AND ALIGNMENT PROCEDURES) AND TO FINAL OR PERMANENT AREAS, THE VARIANCE HOLDER WILL RETAIN THE RECORDS OF THESE PROCEDURES AND THE RESULTS OF ALL TESTS AS REQUIRED BY 21 CFR 1002.31, A COPY OF THE VARIANCE APPLICATION, THE APPROVAL LETTER, CURRENT PROCEDURES, AND RECORDS RELATING TO EACH PARTICULAR SHOW WILL BE WITH THE OPERATOR OR OTHER RESPONSIBLE INDIVIDUAL AND WILL BE MADE AVAILABLE FOR INSPECTION BY FDA AND OTHER RESPONSIBLE AUTHORITIES.

1. [X] ADVANCE WRITTEN NOTICE WILL BE MADE AS EARLY AS POSSIBLE TO APPROPRIATE FEDERAL, STATE, AND LOCAL AUTHORITIES PROVIDING SHOW ITINERARY WITH DATES AND LOCATIONS CLEARLY AND COMPLETELY IDENTIFIED, AND A BASIC DESCRIPTION OF PROPOSED EFFECTS INCLUDING A STATEMENT TO THE MAXIMUM POWER OUTPUT INTENDED. SUCH NOTIFICATIONS WILL BE MADE, BUT NOT NECESSARILY BE LIMITED, TO;
- (1) THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, OFFICE OF COMPLIANCE (HFZ-312), 8757 GEORGIA AVE., SILVER SPRINGS, MD 20910, PROVIDING THE INITIAL AND CLOSING DATES FOR FIXED INSTALLATIONS AND THE ITINERARY FOR MOBILE SHOWS. IN ADDITION, UNLESS ALL ASPECTS OF SUCH SHOW HAVE BEEN REPORTED AND THE ACCESSION NUMBERS CLEARLY REFERENCED, EACH NOTICE WILL INCLUDE DESCRIPTIONS OF EACH SHOW AND A LISTING OF ALL EFFECTS TO BE PERFORMED IN SUFFICIENT DETAIL TO CONFIRM COMPLIANCE WITH THE REGULATIONS AND THIS VARIANCE.
 - (2) THE FEDERAL AVIATION ADMINISTRATION (FAA) FOR ANY PROJECTIONS INTO OPEN AIRSPACE AT ANY TIME (I.E., INCLUDING SET-UP, ALIGNMENT, REHEARSALS, PERFORMANCES, ECT.). IF THE FAA OBJECTS TO ANY LASER EFFECTS, THE OBJECTIONS WILL BE RESOLVED AND ANY CONDITIONS REQUESTED BY FAA WILL BE ADHERED TO, IF THESE CONDITIONS CAN NOT BE MET, THE OBJECTIONABLE EFFECTS WILL BE DELETED FROM THE SHOW.
 - (3) STATE AND LOCAL RADIATION CONTROL OFFICES/AGENCIES FOR ALL SHOWS TO BE PERFORMED WITHIN THEIR JURISDICTIONS, ALL REQUIREMENTS OF STATE AND LOCAL LAW WILL BE SATISFIED AND ANY OBJECTIONS RAISED BY LOCAL AUTHORITIES WILL BE RESOLVED OR THE EFFECTS DELETED. (LISTS OF FEDERAL AND STATE OFFICES ARE AVAILABLE FROM THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH UPON REQUEST.)

14. REMARKS

George Carden Circus International will only use equipment from companies manufacturing certified projectors. From time to time rental equipment will be required in the normal course of business, in the event rental equipment is used we will only use equipment from companies with a proper and current CDRH variance.

SAMPLE: Las Vegas Lasers & Certified Projectors from companies holding a proper CDRH Variance.

CERTIFICATION

I CERTIFY that all of the above information and statements are true, complete and correct to the best of my knowledge and acknowledge that my variance application may be denied or my variance may be revoked if this application is found to be false, misleading, or incorrect in any material way. I have submitted and will submit all reports by 21 CFR 1002.10 and 1002.12 on the laser equipment and show(s). I further understand that I may be required by regulation or by the Director, Center for Devices and Radiological Health, to supply such other information as may be necessary to evaluate and act on this application.

15. SIGNATURE:

16. NAME (type or print)

Robert J Ruhl

17. TITLE

Safety Officer

REPORT ON LASER LIGHT SHOW OR DISPLAY*

PART 1 IDENTIFICATION OF MANUFACTURER

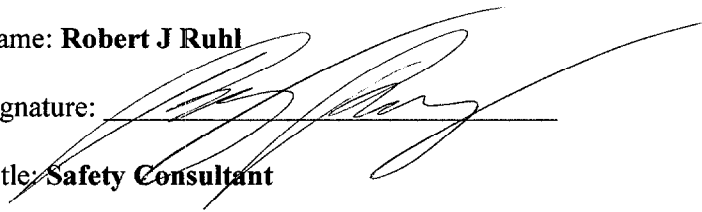
1.1 Manufacturer

- a. Name of light show manufacturer: **George Carden Circus International**
- b. Address: Street: **3901 West State Hwy. O**
City: **Springfield**
State: **MO** Zip Code: **65803**
- c. Area code and telephone: **(417) 833-3588**

1.2 Importer (if applicable):

- a. Name of importer
- b. Address: Street
City
State Zip Code
- c. Area code and telephone ()

1.3 Name, signature, and title of person preparing this report

- a. Name: **Robert J Ruhl**
- b. Signature: 
- c. Title: **Safety Consultant**

*
Information on laser projectors is to be submitted using "Guide for Preparing Initial Reports and Model Change Reports on Lasers and Products Containing Lasers," HHS Publication (F)A 86-8259.

PART 2

IDENTIFICATION OF REPORT

2.1 Is this report pursuant to paragraph (c) of 21 CFR 1002.61?
(**x**)Yes ()No

2.2 This report is
() an initial report
() a model change report
(**x**) a supplemental report

2.3 If this is a supplemental report, give CDRH accession number and date of the initial or model change report that it supplements.

Accession number: 97A0089

Date: March 26 -1997

2.4 Date of this report : Tuesday, June 5, 2000

PART 3

SHOW NAME

- 3.1 What is (are) the name(s) or the light show or display?

PART 4

VARIANCE

- 4.1 Attach a copy of your variance application (FDA Form 3147) or, if approved, your variance approval letter (or variance number).

See Attachment to Part 4.1

PART 5

PROJECTION EQUIPMENT

- 5.1 List each projector used in the light show by manufacturer, model number or other designation, and CDRH accession number for the projector if known.

<u>Manufacturer</u>	<u>Model or designation</u>	<u>CDRH accession number</u>
<u>Las Vegas Laser</u>	<u>LT-1 000</u>	<u>91V-0509</u>

PART 6
SHOW VENUE

6.1 The laser light show or display takes place in:

- ☒ Planetarium or other dome projection structure
- ☒ Theater
- ☒ Hotel/Motel ballroom or meeting room
- ☒ Store displays
- ☒ Trade show or convention
- ☒ Discotheque or nightclub
- ☒ Pavilion
- ☒ Indoor arena
- ☒ Outdoor arena
- ☒ Museum
- ☒ Outdoor unenclosed area
- ☒ Other (specify)

AS PER NOTIFICATION

6.2 The laser light show or display takes place:

- ☒ at only one (fixed) location
- ☒ at a variety of (tour) locations
- ☒ Other (specify)

AS PER NOTIFICATION

PART 7

SHOW LOCATIONS, DATES, TIMES

- 7.1 Give specific location(s), date(s), and time(s) for the show, if known.*

AS PER NOTIFICATION

PART 8

SHOW EFFECTS PRODUCED

- 8.1 The laser light show uses the following laser effects:

 x front screen projections

 x rear screen projections

 x holographic displays

 x multiple reflection/diffraction effects

 audience scanning, including scanning any accessible, uncontrolled areas

 x reflections from stationary mirrors or mirrored surfaces

 x stationary irradiation of rotating mirror balls or other mirrored shape

 x scanning irradiation of rotating mirror balls, etc

 x fiber optic projections

 x fog, smoke, or other scattering effects

 x other(specify)

AS PER NOTIFICATION

*see footnote 1 at the end of this Guide

PART 9

DIAGRAMS AND DRAWINGS OF SHOW VENUE

- 9.1 Provide both plan and elevation drawings with dimensions of the show or display. If the setup varies from show to show, then provide this information for a typical show. Include in the drawings the location of the projector(s) and control panel(s), audience, performer(s), operator(s), mirrors, mirror balls, display screens (or other targets), and beam termination points.

Show the direct and reflected laser radiation beam paths. Provide the laser radiation levels in each beam including the wavelengths, peak and average power, and scan parameters (if scanned) for the worst case from a human access point of view. Be sure the drawings indicate the minimum separations of the laser radiation fields (or beams) from reference locations in audience and performer areas in both vertical and horizontal directions, and any direct or reflected beams into audience or performer locations.

Drawings attached? ☒ Yes () No (If "No," explain why)

SEE ATTACHMENT TO PART 9.1

PART 10

LASER RADIATION LEVELS

- 10.1 Describe how each of the laser radiation levels, indicated above, were determined. If any levels were derived from calculations rather than directly measured, provide the actual calculations that were made.

Description and calculations enclosed? ☒ Yes () No.

Our use of lasers and power levels for any display would fall within general light show industry normal levels and the capability of our existing equipment.

EXAMPLE'S :based on laser light show display and practices.

- 1. Beam Effects from 2 to 40 Watts**
- 2. Screen effects from 1/2 to 5 Watts**

All other effects would be at minimum power levels.

PART 11

SCANNING SAFEGUARDS

- 11.1 Will there be audience scanning* from any of the planned effects?

☐ Yes ☒ No

- 11.2 Do any of the planned effects require laser radiation (direct or scanned beams) to be viewed by operators, performers, or employees?

☐ Yes ☒ No

If the answer to either of the above questions is yes; describe how the radiation levels that reach into audience areas are maintained within the limits of Class I. If Class I limits are maintained by scanning, your description must include details of the required scan failure safeguard, including a discussion of the means of detection of the scanning, the theory of the operation of the scanning safeguard, and its speed of response.

Description attached? ☐ Yes ☒ No (If "No," explain why)

NOT APPLICABLE

- 11.3 Will any laser radiation greater than Class I STRIKE BUT NOT BE VIEWED by operators, performers, or other employees?

☐ Yes ☒ No

If "Yes," describe, in detail, the operation of the scan failure safeguard or other means which will prevent exposure to beams exceeding Class II. If a scan safeguard is used, include a discussion of the detection of scanning, the theory of operation, and the speed of response of the safeguard. If other means are used, such as pressure pads or infrared beams, describe in detail as well.

Description attached? ☐ Yes ☒ No (if "No" explain why)

NOT APPLICABLE

*see footnote 2 at the end of this Guide

PART 12

OPERATOR CONTROLS

12.1 Is the show under the continuous control of an operator? (x) Yes () No

12.2 Does the laser operator perform tasks in addition to operation of the laser projector?

(x) Yes () No (If "Yes," describe those tasks)

Equipment maintenance, equipment alignment, equipment set-up, and Laser Safety.

12.3 Can the operator see all the propagating beam paths, their terminations, and the audience at all times during the performance?

(x) Yes () No (If "No," explain how adequate surveillance is provided)?

12.4 Do any other personnel assist in providing surveillance of the laser display?

(x) Yes () No

If "Yes;" state number of persons, their identification, and how they assist in providing surveillance.

Information attached? (x) Yes () No (If "No," explain why)

Operator's assistant, Staff from show venue will be enlisted if necessary and if available, to assist the operator with observing effects the operator may not be able to see directly.

12.5 What qualifications are required of laser operators for your show?*

All operators will be familiar with laser hazards, safety regulations, and have no less than 4 weeks training.

* see footnote 3 at the end of this Guide

OPERATOR CONTROLS (Continued)

- 12.6 If your show is not under the continuous control of an operator, is a person designated to be responsible for the immediate termination of the laser radiation in the event of equipment malfunction, audience unruliness, or other unsafe conditions?

(x) Yes () No () Not applicable
(If "No, "explain alternate control)

- 12.7 How is this person designated? What are his or her other duties?

NOT APPLICABLE

- 12.8 What qualifications are required of this person?

NOT APPLICABLE

PART 13 PROJECTION EQUIPMENT CONTROLS

- 13.1 Are one or more readily accessible controls provided to immediately terminate laser radiation?
(x) Yes () No

Number of controls: 3

- 13.2 Describe the location of these controls and their operation relative to your show.

Control #1. Beam Attenuation on the projector

Control #2. Key Switch on the projector

Control #3. Key Switch on the laser power supply

PART 14

TEST PROCEDURES

- 14.1 Attach a copy of the written setup, alignment, and test procedures to be followed prior to the operation of the laser light show at each location (see sample checklist for laser light shows in Appendix).

Procedures attached? ☒ Yes () No (If "No," explain why)

SEE ATTACHMENT TO PART 14.1

- 14.2 When are these setup, alignment, and test procedures performed?

Before all shows

- 14.3 What laser radiation levels are used during setup, alignment, and checkout?
250 milliwatt Approximated or at lowest possible power levels of equipment being used.

- 14.4 Is a record of the results of the setup, alignment, and test procedures maintained?
☒ Yes () No

If "No," explain how adequate quality assurance is maintained.

NOTE: Adequate record keeping would include, but not be limited to: (1) sketches showing the location of the laser projector(s), operator(s), performer(s), audience, beam paths, viewing screens, wall mirrors, mirror balls, and other surfaces that may be struck by the laser beams; (2) information on scanning patterns, velocity, and frequency; and (3) laser radiation levels used in each effect.

PART 15

NOTIFICATION PROCEDURES

- 15.1 What procedures are followed for notification of appropriate Federal (CDRH, FAA), State, and local agencies?

SEE ATTACHMENT TO PART 15.1

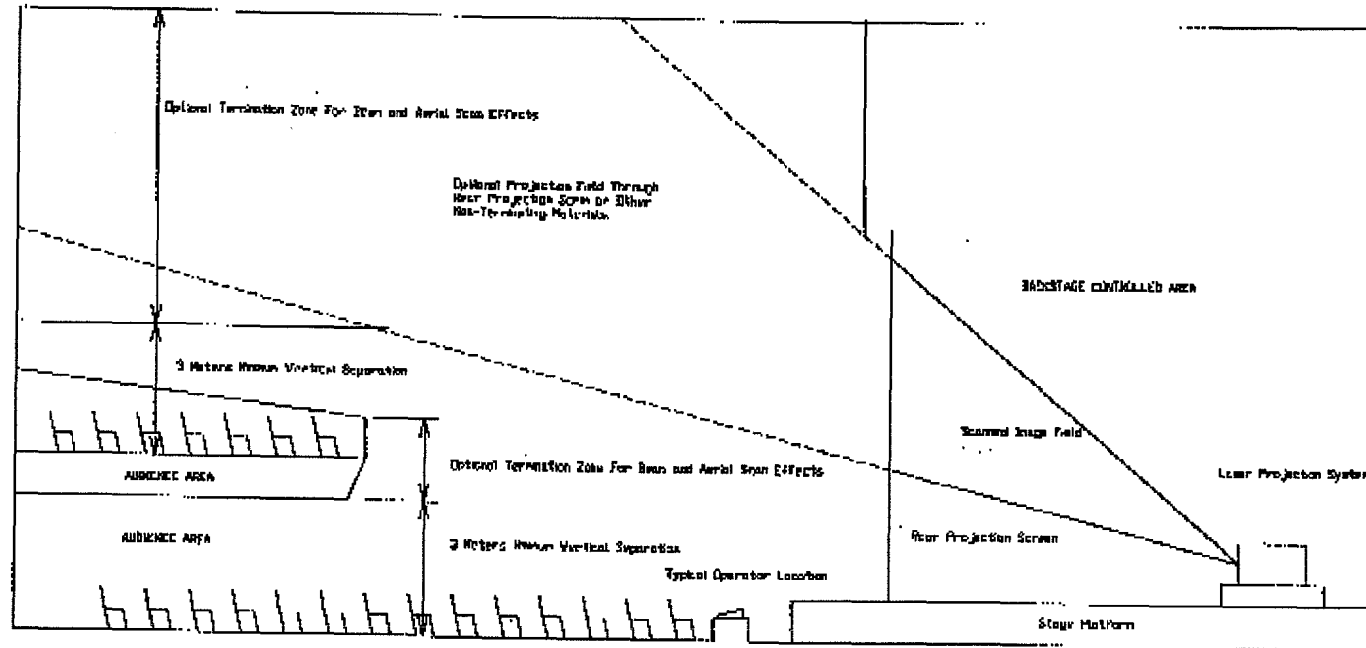
Procedures and/or form letters attached? ☒ Yes ☐ No (If "No," explain. why)

- 15.2 What Federal, State, or local agencies are notified or 'would be notified? List of agencies attached:
(x) Yes ☐ No (If "No," explain why)

SEE ATTACHMENT TO PART 15.2

ATTACHMENT TO PART 9.1

TYPICAL INDOOR REAR PROJECTION CONFIGURATION - ELEVATION VIEW

[illegible]

ATTACHMENT TO PART 14.1

Equipment Setup Checklist

Setup Show 1 Show 2 Show 3

Show Date:

Show Name:

Basic Safety:

- 1 All protective covers properly fit and secured
- 2 Covers are adequate to prevent access to excessive radiation
- 3 Beam Masking in place to prevent undesired exposure to laser radiation
- 4 Laser Scatter is adequately controlled to prevent excessive radiation levels
- 5 All beam shutters operating properly
- 6 Key switch(es) functional
- 7 Emission indicator functional
- 8 Emission delays operating
- 9 Check interlocks
- 10 Intercrew Communication systems checked and functioning properly
- 11 Safety Spotters in place viewing laser output, audience and aircraft
- 12 Check function of manual reset system on exciter
- 13 Check remote interlock connector and function

Projector Label Verification:

- 1 Manufacturer's Certification Label
- 2 Show/Performance Manufacturer's Identification Label
- 3 Warning Logotype
- 4 Aperture labels
- 5 Emission Indicator labels
- 6 Non-Interlock label (if applicable)
- 7 Defeatable Interlock label (if applicable)

Other Safety Feature Verification:

- 1 Warning labels posted throughout venue
- 2 Laser safety area(s) secure
- 3 Beams no closer to audience than 3 meters vertical
- 4 Beams no closer to audience than 2 meters horizontal

Alignment:

- 1 Only qualified personnel - no audience present
- 2 Beam targets - no audience present
- 3 All targets secured in place
- 4 Laser energized and projector alignment with lowest laser power possible
- 5 Energized laser with shutter closed
- 6 All power levels determined and recorded
- 7 Check scan test pattern
- 8 Any problems found?

Inspections:

- 1 Was there a State Inspection at this performance?
- 2 Any State violations observed?
- 3 If so, were they resolved?
- 4 Was there a CDRH Inspection at this performance?
- 5 Any CDRH violations observed?
- 6 If so, were they resolved?

Attachment to Part 14.1

**DAILY PERFORMANCE LIST
LASER LIGHT SHOW**

Show Date: _____

Show Time: _____

Operator: _____

Venue Name: _____

Venue Location: _____

All items must be brought into a satisfactory state prior to the operation / or being checked off. If an item fails to meet performance standards consult your supervisor. Do not attempt to run any show with any deficiency in performance standards. Include power levels, and remedies for any potential CDRH violations use reverse side if necessary.

Attachment to Part 15.1

STATE NOTIFICATIONS

Most states require notification concerning shows taking place within their borders. Requirements for notifications vary widely so it is wise to check with the proper authority. To reach the proper authority contact:

Manuel Karos (301) 594-4648 x 149
Sean Boyd (301) 594-4654

The responsibility to contact the state authority is that of the manufacturer **George Carden Circus International.**

For the following states: California, Nevada, Washington, Idaho, Montana, Arizona, Hawaii, and Alaska contact

Gary Zaharek, EOS FDA (HFR-PA1530) 96 N Third Street, San Jose CA 95112
Voice (408) 291-7549 Fax (409) 291-7228

For Texas:

Texas Department of Health, Bureau of Radiation Control, 1100 West 49th St., Austin, TX 78756
Voice (512) 834-6688 Fax (512) 834-6690

Attachment to part 15.1

Notification to State, Federal, and Local, Officials will be no less than 2 weeks whenever possible. FAA Notifications will be 4 to 6 weeks. In the case of less than one (1) week notice, notification will be sent by fax to CDRH and appropriate authorities.

ATTACHMENT TO PART 15.1

NOTIFICATION TO CDRH OF SHOW

1. Company Name: George Carden Circus International
2. Address of Company: 3901 West State Hwy. O
3. Name of responsible person: Charles V. Amaral, Jr.
4. Signed By: _____
5. Telephone No: 1 (417) 833-3588
6. Date of submission: 00 - 00 - 2000
7. Docket Number 97V-0095

VENUE LOCATION:

Venue: _____
Street: _____
City: _____
State: _____
Contact: _____
Venue Phone: _____
Dates: Start: _____ End: _____

Number of Scheduled Shows Per Day () Total Number of Shows ()
Times Start: : AM () PM () End: : AM () PM ()

VARIANCE IS REQUESTED FOR	SHOW WILL RUN IN THIS LOCATION
---------------------------	--------------------------------

A. ☒ A Laser Light Show

B. ☐ Days ☐ Weeks ☐ Months

C: SHOW WILL BE IN A	D: PRODUCT UTILIZES THE FOLLOWING EFFECTS
<p>C.</p> <p><input type="checkbox"/> Planetarium or other dome projections structure</p> <p><input type="checkbox"/> Theater</p> <p><input type="checkbox"/> Hotel/Motel Ballroom or Meeting room</p> <p><input type="checkbox"/> Trade Show or Convention</p> <p><input type="checkbox"/> Discotheque or Night Club</p> <p><input type="checkbox"/> Pavilion</p> <p><input type="checkbox"/> Indoor Arena</p> <p><input type="checkbox"/> Outdoor Arena</p> <p><input type="checkbox"/> Museum</p> <p><input type="checkbox"/> Outdoor Unenclosed Area</p> <p><input type="checkbox"/> Other (Specify):</p>	<p>D.</p> <p><input type="checkbox"/> Front Screen Projections</p> <p><input type="checkbox"/> Rear Screen Projections</p> <p><input type="checkbox"/> Holographic Displays</p> <p><input type="checkbox"/> Multiple Reflection/Diffraction Effects</p> <p><input type="checkbox"/> Audience Scanning</p> <p><input type="checkbox"/> Reflections From Stationary Mirrors</p> <p><input type="checkbox"/> Stationary Irradiation of Rotating Mirror Balls</p> <p><input type="checkbox"/> Scanning irradiation of Rotating Mirror Balls</p> <p><input type="checkbox"/> Fiber Optic Projections</p> <p><input type="checkbox"/> Fog, Smoke, or Scattering Enhancement Effect</p> <p><input type="checkbox"/> Other (Specify):</p>

ALL NECESSARY: FEDERAL, STATE, CITY, COUNTY, AGENCIES HAVE BEEN NOTIFIED.

Mail and Fax this application to:

Center for Devices and Radiological Health
Office of Compliance (HFZ-342)
2098 Gaither Road
Rockville, MD 20850
Fax Number (301) 594-4672

Attachment to Part 15.2

For States: ME, NH, MA, NY, CT, RI

Max Lager, EOS
FDA (HFR-NE25)
1 Montvale Avenue
Stomeham, MA 02180.3542

Voice (617) 279-1675 ext 154
Fax (617) 279-1742

For States: NJ, DE, MD, VA, TN, NC, SC, GA, FL, PR, MS, LA

Dennis Butcher, EOS
FDA, (HFR-SE18)

Voice (404) 347-3576 ext 5259
Fax (404) 347-4349

For States: PA, WV, KY, OH, IL, MI, WI, MN, ND, SD

James E, Frye, EOS
FDA, (HFR-MA450)
1141 Central Parkway
Cincinnati, OH 45202

Voice (513) 684-3505
Fax 513) 684-2905

For States IA, MO, AR, NE, KS, TX, WY, CO, NM, UT

Tom Goertz
FDA, Southwest Region (HFR-SW14)
7920 Elmbrook, Suite 102
Dallas, TX 75247

Voice (204) 655-8100 ext 141
Fax (204) 655-8130

For States AZ, Southern California

Ralph L, Kirch, Engineer
FDA, (HFR-PA2530)
4615 E, Elwood Street, Room 200
Phoenix, AZ 85040

Voice (602) 379-4595 Ext 224

Backup for Los Angeles

Serrah Namini, EOS
FDA (HFR-PA2545)
18004 Skypark Circle, Suite 140
Irvine, CA 92714

Voice (714) 836-2377
Fax (714) 836-2878

For States: CA, NV, MT, ID, OR, WA, AK, HI

Gary Zaharek, EOS
FDA (HFR-PA1530)
96 N Third Street
San Jose, CA 95112

Voice (408) 291-7549
Fax (408) 291-7228

1 From
 Date **7-11-2000**

Sender's Name **Bob Ruhl** Phone **509 924-0661**

Company **Associated Laser Productions**

Address **E 8309 BROADWAY**

City **Spokane** State **WA** ZIP **99217**

2 Your Internal Billing Reference

3 To
 Recipient's Name _____ Phone _____

Company **Dockets Management Branch (HFA-305)**

Address **Food and Drug Administration Room 1-23**

We cannot deliver to P.O. boxes or P.O. ZIP codes.

12420 PAACKLAWN DRIVE

City **Rockville** State **MD** ZIP **20852**



4a Express Package Service
☐ FedEx Priority Overnight
☐ FedEx Standard Overnight
☒ FedEx Express Saver*
☐ FedEx 2Day*
 Packages up to 150 lbs. Delivery commitment may be later in some areas. FedEx Letter Rate not available. Minimum charge: One-pound rate.

4b Express Freight Service
☐ FedEx 1Day Freight*
☐ FedEx 2Day Freight
☐ FedEx 3Day Freight
 Packages over 150 lbs. Delivery commitment may be later in some areas.

5 Packaging
☐ FedEx Letter*
☐ FedEx Pak*
☐ Other Pkg.
* Declared value limit \$500. Includes FedEx Box, FedEx Tube, and customer pkg.

6 Special Handling
☐ Saturday Delivery
☐ Sunday Delivery
☐ HOLD Weekday at FedEx Location
☐ HOLD Saturday at FedEx Location
 Does this shipment contain dangerous goods? One box must be checked.
☐ No ☐ Yes ☐ Yes ☐ Dry Ice
 As per attached Shipper's Declaration Shipper's Declaration not required Dry Ice, 9 UN 1845 x kg
 Dangerous Goods cannot be shipped in FedEx packaging. ☐ Cargo Aircraft Only

7 Payment Bill to: Enter FedEx Acct. No. or Credit Card No. below.
☒ Sender ☐ Recipient ☐ Third Party ☐ Credit Card ☒ Cash/Check
Obtain Recip. Acct. No.

Total Packages	Total Weight	Total Declared Value†	Total Charges
1	2	\$.00	10.19
			<small>Credit Card Auth.</small>

8 Release Signature Sign to authorize delivery without obtaining signature.

By signing you authorize us to deliver this shipment without obtaining a signature and agree to indemnify and hold us harmless from any resulting claims.
Questions? Call 1-800-Go-FedEx® (800-463-3339)
 Visit our Web site at www.fedex.com
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360